IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **ARAKI et al.**

U.S. Patent Application No.: **09/806,925** Group Art Unit: **1651**

Filed: **June 20, 2001** Examiner: **Ruth A. Davis**

For: **PREVENTATIVES OR REMEDIES FOR INFECTION, ANTI-ENDOTOXIN AGENTS, VACCINE ADJUVANTS AND GROWTH PROMOTERS**

AMENDMENT AND RESPONSE

Mail Stop Amendment
Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action dated June 10, 2006, relating to the above-identified application, Applicant hereby requests reconsideration of the rejections for the reasons given below. This response is considered timely since it is being filed within five months of the issuance of the Office Action and a petition for a two-month extension of time and the extension fee are enclosed herewith. Should it be determined that a fee is due, the Director is authorized to charge such a fee to Deposit Account No. 50-0462.

Please amend the above-identified application as set forth below.

Amendments in the Claims are shown in the list of claims that begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

IN THE CLAIMS:

1-152. (Canceled)

153. (Currently amended) A method for remedying a disease caused by an infection in humans or animals comprising the step of:

orally administering an amount of a sugar cane-derived extract as an active ingredient to a human or animal after infection with the disease, which amount is effective to remedy said disease and wherein said infection is an *Escherichia coli* infection, and the sugar cane-derived extract is a fraction ~~obtainable by~~obtained by passing a raw material selected from the group consisting of sugar cane juice, a liquid extract from sugar cane, and sugar cane-derived molasses, through a column packed with a synthetic adsorbent as a fixed carrier, and eluting substances adsorbed on the synthetic absorbent with a solvent selected from the group consisting of water, methanol, ethanol and mixtures thereof, said sugar cane derived-extract containing less ~~saccharide~~ sugar than said raw material.

154-155. (Canceled)

156. (Currently amended) A method for remedying a disease caused by an infection in humans or animals comprising the step of:

orally administering an amount of a sugar cane-derived extract as an active ingredient to a human or animal after infection with the disease, which amount is effective to remedy said disease, wherein said infection is an *Escherichia coli* infection, and the sugar cane-derived extract is a fraction which absorbs light of a wavelength of 420 nm ~~obtainable by~~obtained by column chromatographic treatment utilizing differences in affinity for an ion exchange resin packed in a column as the fixed carrier, said sugar cane-derived extract containing less ~~saccharide~~sugar than a composition from which said sugar cane-derived extract is extracted.

157. (Previously presented) The method according to claim 156, wherein the ion exchange resin is a cation exchange resin.

158. (Previously presented) The method according to claim 157, wherein the cation exchange resin is a strongly acidic cation exchange resin.

159. (Previously presented) The method according to claim 158, wherein the strongly acidic cation exchange resin is of a sodium ion form or a potassium ion form.

160. (Previously presented) The method according to claim 156, wherein the ion exchange resin is a gel form resin.

161. (Previously presented) The method according to claim 156, wherein ion exchange chromatographic treatment is carried out in a pseudo moving-bed continuous separation method.

162. (Previously presented) The method according to claim 156, wherein the fraction absorbing light of a wavelength of 420 nm is further treated by electrodialysis to thereby decrease a salt content of the fraction.

163-165. (Canceled)

166. (Previously presented) The method according to claim 153, wherein the sugar cane-derived extract is administered in the form of food, which comprises the sugar cane-derived extract.

167. (Previously presented) The method according to claim 166, wherein the food is an animal feed.

168-182. (Canceled)

183. (Currently amended) A method for remedying a disease caused by a viral infection in humans or animals comprising the step of:

orally administering an amount of a sugar cane-derived extract comprising a component having a molecular weight less than 1,000 as an active ingredient, to a human or animal after infection with the disease by a Pseudorabies infection, which amount is effective to remedy said disease,

wherein the sugar cane-derived extract is a fraction ~~obtainable by~~obtained by passing a raw material selected from the group consisting of sugar cane juice, a liquid extract from sugar cane and a sugar-cane-derived molasses, through a column packed with a synthetic adsorbent as a fixed carrier, and eluting substances adsorbed on the synthetic adsorbent with a solvent selected from the group consisting of water, methanol, ethanol and mixtures thereof, said sugar cane derived-extract containing less ~~saccharide~~sugar than said raw material.

184. (Canceled)

185. (Currently amended) A method for remedying a disease caused by a viral infection in humans or animals comprising the step of:

orally administering an amount of a sugar cane-derived extract comprising a component having a molecular weight of less than 1000 as an active ingredient, to a human or animal after infection with the disease by a Pseudorabies infection, which amount is effective to remedy said disease, and the sugar cane-derived extract is a fraction which absorbs light of a wavelength of 420 nm ~~obtainable by~~obtained by column chromatographic treatment utilizing differences in affinity for an ion exchange resin packed in a column as the fixed carrier, said sugar cane-derived extract containing less ~~saccharide~~sugar than a composition from which said sugar cane-derived extract is extracted.

186. (Previously presented) The method according to claim 185, wherein the ion exchange resin is a cation exchange resin.

187. (Previously presented) The method according to claim 186, wherein the cation exchange resin is a strongly acidic cation exchange resin.

188. (Previously presented) The method according to claim 187, wherein the strongly acidic cation exchange resin is of a sodium ion form or a potassium ion form.

189. (Previously presented) The method according to claim 185, wherein the ion exchange resin is a gel form resin.

190. (Previously presented) The method according to claim 185, wherein ion exchange chromatographic treatment is carried out in a pseudo moving-bed continuous separation method.

191. (Previously presented) The method according to claim 185, wherein the fraction absorbing light of a wavelength of 420 nm is further treated by electrodialysis to thereby decrease a salt content of the fraction.

192. (Previously presented) The method according to claim 183, wherein the sugar cane-derived extract is administered in the form of food, which comprises the sugar cane-derived extract.

193. (Previously presented) The method according to claim 192, wherein the food is an animal feed.

194. (Currently amended) A method for remedying a disease caused by a viral infection in humans or animals comprising the step of:

administering an a amount of a sugar cane-derived extract comprising a component having a molecular weight less than 1,000 as an active ingredient, to a human or animal after infection with the disease by a Pseudorabies infection, which amount is effective to remedy said disease, by a method of administration selected from the group consisting of intravenous, intramuscular, subcutaneous, intracutaneous, intra-abdominal, intra-rectal, hypoglossal and instillation, and

wherein the sugar cane-derived extract is a fraction ~~obtainable by~~obtained by passing a raw material selected from the group consisting of sugar cane juice, a liquid extract from sugar cane, and a sugar cane-derived molasses through a column packed with a synthetic adsorbent, and eluting substances adsorbed on the synthetic adsorbent with a solvent selected from the group consisting of water, methanol, ethanol and mixtures thereof, said sugar cane derived-extract containing less ~~saccharide~~sugar than said raw material.

195. (Canceled)

196. (Currently amended) A method for remedying a disease caused by a viral infection in humans or animals comprising the step of:

administering an amount of a sugar cane-derived extract comprising a component having a molecular weight of less than 1000 as an active ingredient, to a human or animal after infection with the disease by a Pseudorabies infection, which amount is effective to remedy said disease, by a method of administration selected from the group consisting of intravenous, intramuscular, subcutaneous, intracutaneous, intra-abdominal, intra-rectal, hypoglossal and instillation, and the sugar cane-derived extract is a fraction which absorbs light of a wavelength of 420 nm ~~obtainable by~~obtained by column chromatographic treatment utilizing differences in affinity for an ion exchange resin packed in a column as the fixed carrier, said sugar cane-derived extract containing less ~~saccharide~~sugar than a composition from which said sugar-cane derived extract is extracted.

197. (Previously presented) The method according to claim 196, wherein the ion exchange resin is a cation exchange resin.

198. (Previously presented) The method according to claim 197, wherein the cation exchange resin is a strongly acidic cation exchange resin.

199. (Previously presented) The method according to claim 198, wherein the strongly acidic cation exchange resin is of a sodium ion form or a potassium ion form.

200. (Previously presented) The method according to claim 196, wherein the ion exchange resin is a gel form resin.

201. (Previously presented) The method according to claim 196, wherein ion exchange chromatographic treatment is carried out in a pseudo moving-bed continuous separation method.

202. (Previously presented) The method according to claim 196, wherein the fraction absorbing light of a wavelength of 420 nm is further treated by electrodialysis to thereby decrease a salt content of the fraction.

203. (Previously presented) The method according to claim 194, wherein the sugar cane-derived extract is administered in the form of food, which comprises the sugar cane-derived extract.

204. (Previously presented) The method according to claim 203, wherein the food is an animal feed.

205. (Previously presented) The method according to claim 156, wherein the sugar cane-derived extract is administered in the form of a food, which comprises the sugar cane-derived extract.

206. (Previously presented) The method according to claim 205, wherein the food is an animal feed.

207. (Previously presented) The method according to claim 185, wherein the sugar cane-derived extract is administered in the form of a food, which comprises the sugar cane-derived extract.

208. (Previously presented) The method according to claim 207, wherein the food is an animal feed.

209. (Previously presented) The method according to claim 196, wherein the sugar cane-derived extract is administered in the form of a food, which comprises the sugar cane-derived extract.

210. (Previously presented) The method according to claim 209, wherein the food is an animal feed.

REMARKS

By this amendment, claims have been amended. Upon entry of this amendment, claims 153, 156-162, 166-167 and 183, 185-194 and 196-210 will be pending in the present application.

Claims 153, 156, 183, 185, 194 and 196 have been amended to replace the term, "less saccharide" with the term, "less sugar." Basis for this amendment is found at page 21, line 14 of the application as originally filed.

Claims 153, 156, 183, 185, 194 and 196 have been amended to replace the phrase, "obtainable by" with the phrase, "obtained by" in order to require that the claimed extract be obtained in the manner claimed in order to absolutely require that the product is obtained by the claimed process, as suggested by the Examiner on page 6, 2nd paragraph of the "Response to Arguments" section of the Office Action.

The 35 U.S.C. 112 Rejections

Claims 153, 156-162, 166-167, 183, 185-194 and 196-210 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement on the basis that the term, "containing less saccharides" is not supported by the specification as originally filed. Although the applicant does not concede the correctness of this rejection, the applicant has amended the claims to replace all occurrences of this phrase with the phrase, "containing less sugar." Basis for this amendment is found on page 21, line 14 of the application as originally filed. Favorable consideration and withdrawal of the rejection in view of the claim amendments is requested.

The Rejection Under 35 U.S.C. §103(a)

Claims 153, 156-162, 166-167, 183, 185-194 and 196-210 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bermudez, Kawai, Saska, Agar, Brewer and Kearny. This rejection, at least insofar as it applies to claims 153, 156-162, 166-167 and 182-183, 185-194 and 196-204, as amended, is respectfully traversed and reconsideration is requested for the reasons that follow.

The Examiner dismissed applicants previous arguments in the Office Action dated January 10, 2006 (hereinafter "the Office Action") on the sole basis that,

> "...these arguments fail to persuade because the instant claims do not require that the extract be obtained in the manner claimed, but that it is obtainable by the claimed methods. Thus, the claims do not absolutely require that the product must be obtained by any particular process."

See the Office Action, page 6, 2nd paragraph of the "Response to Arguments" section. The claims have now been amended to require that the extract be obtained by the claimed methods. Thus, the sole reason given by the Examiner for dismissing applicant's arguments presented below has been obviated by amendment of the claims to require that the claimed extract be obtained by the claimed process. Accordingly, it is considered that the present claims, as amended, are clearly patentable over the prior art for the reasons given below.

Bermudez discloses a method for preparing compositions useful in anti-adhesive therapies, comprising two heating steps (ii)-(iii) as seen on page 3, lines 1 to 10 and page 5, lines 12 to 27 of Bermudez. Heating step (ii) heats the filtered liquid extract at a temperature of from about 60°C to about 70°C for a time period of about 30 to about 60 minutes. Heating step (iii) heats the liquid extract obtained in heating step (ii) at a temperature of from about 130°C to about 165°C for about 24 hours. Bermudez also discloses that it is important that the extract reach a temperature of at least 150°C (i.e. the boiling point) as seen on page 5, lines 26 to 27 of Bermudez. The resulting product, Bercedin, is described on page 6 of Bermudez.

The Examiner takes the position that, "Bermudez teaches methods for treating bacterial and viral infections, the method comprising administering effective amounts of sugar cane extracts." See page 4, lines 4-5 of the Office Action. The applicant respectfully disagrees with this conclusion for the following reasons.

First, the passage relied on by the Examiner on page 2 of Bermudez actually reads, "The present invention provides therapeutic compositions, preferably derived from sugar cane, which contain primarily saccharide... components..." (emphasis added). See p. 2, lines 20-21 of Bermudez. Thus, page 2 of Bermudez does not teach administration of sugar cane extracts but rather, teaches administration of saccharide components. This is a very important distinction as explained below.

Page 4 of Bermudez, also relied on by the Examiner, teaches that, "The compositions are preferably derived from sugar cane by extraction and heating of the extract in a non-fermentation process." See page 4, lines 4-5 of Bermudez. Thus, initially Bermudez obtains a sugar cane

extract. However, the sugar cane extract of Bermudez is then heated to obtain the Bercedin composition that Bermudez discloses as being administered to humans and animals.

From the Summary of the Invention on page 3, lines 8-9 of Bermudez, it is learned that this heating step involves, "(iii) heating the filtered liquid extract at a temperature of from about 130°C to about 165°C for about 24 hours, under agitation." Sugar cane extract, when heated to temperatures in excess of 130°C, undergoes three important chemical changes. These changes are as follows:

(1) At least some sucrose is converted to the reducing sugar glucose,

(2) glucose condenses with amino acids to produce N-glucosylamines via the well-known Maillard reaction, and

(3) saccharides in the sugar cane extract polymerize.

Therefore, the Examiner's statement that Bermudez teaches administration of a sugar cane extract to humans or animals is not correct since what is actually taught by Bermudez is the administration of a composition obtained by chemically reacting a sugar cane extract under conditions of high temperature for an extended time period to polymerize the saccharides. Therefore, the sugar cane extract of Bermudez has been chemically changed in three significant ways by the heating step (iii) and thus is no longer a sugar cane extract obtained by the process claimed in the present claims.

Moreover, it is apparent to the skilled person that the reference to "saccharide components" in Bermudez refers to saccharide polymers of various sugar cane-derived monomers. This is apparent because Bermudez teaches, on page 2, lines 23 to 25 that, "it is believed that heat polymerization of one or more components of the sugar cane extract is required to develop the therapeutic activity of the composition."(emphasis added). Therefore, the heat polymerized carbohydrates or polysaccharides, and not the unpolymerized saccharides contained in a sugar cane extract, are the active components in the Bercedin composition of Bermudez.

Since the sugar cane extract of Bermudez undergoes three significant chemical reactions prior to being administered to humans or animals, this composition clearly does not meet the requirement of claims 153, 166-167, 183, 192-194 and 196-204, that the composition which is administered to a human or animal be obtained by passing a raw material selected from the group consisting of sugar cane juice, a liquid extract from sugar cane, and sugar cane-derived molasses,

through a column packed with a synthetic adsorbent as a fixed carrier, and eluting substances adsorbed on the synthetic absorbent with a solvent selected from the group consisting of water, methanol, ethanol and mixtures thereof. Clearly, the composition of Bermudez that is administered to humans and animals is not the same as a sugar cane extract obtained in this manner since a severe heating step is applied to the product of Bermudez, prior to administration, in order to develop the active ingredients by polymerization of the saccharides, as discussed above. Accordingly, Bermudez does not teach or suggest the administration of the same composition as claimed for administration in any of claims 153, 166-167, 183, 192-194 and 196-204.

The preparation process for sugar cane extract includes the provision of sugar can juice including mill juice obtained by milling sugar cane, extracted juice obtained by extracting sugar cane with water, clarified juice obtained by treating with lime in a sugar mill and concentrated juice. See page 14, lines 13-16 of the specification. To obtain mill juice, warm water is employed but the temperature of the water must be maintained at or below 40°C to avoid dissolution of waxy components from sugar cane in the water which would render the milling machine inoperable. Water used in the process for obtaining extracted juice is typically at about 70-80°C. See George P. Meade, "Spencer-Meade Cane Sugar Handbook NINTH EDITION" – a manual for sugar cane manufacturers and their comes, John, Wiley & Sons, Inc., 1963, page 60, lines 26-27 (copy enclosed), where it is stated that "Steam is also added direct to the diffusing boots and the temperature of the mill-expressed juices other than the first are about 170°F (77°C).

Clarified juice is obtained by clarifying mill juice or extracted juice. In a clarifying process, mill or extracted juice is heated to a temperature of from 90-115°C (See the Spencer-Meade Cane Sugar Handbook, page 82, 2nd line from the bottom to page 91, line 2). According to the Handbook, the temperature of the mill or extracted juice was just above the boiling point, i.e. about 103°C (See the Spencer-Meade Cane Sugar Handbook, page 91, line 5).

In a concentration process, multiple-effect evaporators are usually used for heating, and the liquid temperature is 54-120°C, more generally 96 to 106°C. When sugar liquid is concentrated to a specific sugar concentration in one evaporator, the concentrated sugar liquid is transferred to a next evaporator. The temperature and pressure decrease from one evaporator to the next. The temperature and pressure are such that the sugar liquid boils to evaporate water.

The sugar liquid in the last evaporator has a concentration of about Bx 70, whose boiling point is 100 ± 5.5°C (See the Spencer-Meade Cane Sugar Handbook, page 149, line 7). No further increases in the liquid temperature occur in the multi-effect evaporators. In an alternative process, where the sugar liquid is heated under pressure, a maximum temperature less than 120°C is maintained to avoid a significant reduction in sugar recovery due to polymerization and heat decomposition which occurs at higher temperatures.

In addition, the sugar-cane derived molasses of the present claims also does not undergo a heating step above a temperature of 130°C because sugar cane is chemically changed at such temperatures, which would result in reduced sugar recovery and thus is avoided in the production of molasses. It is well known that molasses is prepared at a temperature of less than 120°C for this reason. Sugar cane-derived molasses includes molasses obtained from a sugar mill and molasses obtained from a sugar refinery. See page 14, lines 23-29 of the specification.

In a sugar mill, sucrose seed crystals are added to the concentrated juice (made as described above) to obtain a mixture of precipitated sucrose crystals and a mother liquid, which is then centrifuged to separate the sucrose crystals, leaving molasses. As mentioned above, no temperature higher than 120°C is applied in the process of obtaining the concentrated juice. In the crystallization of sucrose, the sugar liquid becomes super-saturated to cause boiling point elevation, a reduced pressure pan is employed to maintain the temperature of the boiling sugar liquid at 50-105°C. See e.g. the Spencer-Meade Cane Sugar Handbook, page 191, line 14 where it states that, "...with 83 purity and a strike temperature of 150°F" (66°C).

In a sugar refinery, sucrose crystals obtained from a sugar mill are dissolved in water, which, in turn, is clarified. The juice thus obtained is concentrated using multiple-effect evaporators. No heating over 100°C is applied in any of the clarification, concentration and crystallization steps, where the purity of the sucrose is high and decomposition would be significant at higher temperatures.

Also, use is made of a residue deprived of saccharides from the molasses, such as an isolated liquor obtained in alcoholic fermentation of the molasses. See page 14, lines 9-31 of the specification. Alcohol has a relatively low boiling point, compared to water, and therefore the distillation temperatures in this process remain below 100°C/

Lastly, the liquid extract of sugar cane is obtained by heating a mixture of sugar cane or bagasse, which is obtained by milling in water or warm water, as described above, with water,

methanol, ethanol or a mixture thereof. The boiling points methanol, ethanol, water and mixtures thereof are, 64.65°C, 78.32°C, 100°C and less than 100°C, respectively.

From the foregoing, it is apparent that the raw materials used in the method of the present invention are not subjected to temperatures in excess of 130°C, as required by Bermudez and thus do not contain the polymerized saccharides and decomposition products that are contained in the product of Bermudez which is administered to humans or animals. In summary, the Bermudez product contains more glucose, more polymerized saccharides and more N-glucosylamines than the composition of the present invention since significant amounts of each of these components are produced in the chemical reactions described above which occur in sugar cane extract when heated to temperatures above 130°C as in Bermudez. Accordingly, there is a significant difference between the composition employed in the administration method of the present invention and the composition employed in the administration method of Bermudez.

The Examiner alleges that it would be obvious to employ one or more of the processes of Kawai, Saska et al., Agar et al., Brewer and Kearny to obtain the sugar cane extracts of Bermudez. However, even if this statement is correct, a skilled person still does not arrive at the present invention since Bermudez clearly teaches that sugar cane extracts must be heated at 130-165°C for a 24 hour period to obtain the desired therapeutic activity. As a result, even if the sugar cane extracts of Bermudez are obtained by a process in accordance with Kawai, Saska et al., Agar et al., Brewer and Kearny, the product that is administered to humans and animals in Bermudez is still very different from the product that is administered to humans and animals in accordance with the present invention because of the severe heating step applied by Bermudez.

Kawai, Saska et al., Agar et al., Brewer and Kearney all relate to various aspects of sugar cane extract manufacturing processes. However, none of these references provides any teaching or suggestion which would lead a skilled person to modify the process for making the composition of the primary reference, Bermudez, to eliminate the heating step (iii). As a result, any combination of Bermudez with Kawai, Saska et al., Agar et al., Brewer and Kearney still differs from the present invention in that the Bercedin of Bermudez has undergone three chemical reactions, including polymerization of the saccharides conversion to glucose and the Maillard reaction to produce N-glucosylamines.

In fact, a modification of the teachings of Bermudez to eliminate heating step (iii) would not be obvious since, as discussed above, Bermudez contains a clear teaching that, "...heat polymerization of one or more components of the sugar cane extract is required to develop the therapeutic activity of the composition."(emphasis added). See Bermudez at page 2, lines 23 to 25. Bermudez also teaches that to obtain the compositions useful in anti-adhesive therapies, the process must include the step of "(iii) heating the filtered liquid extract obtained in (ii) at a temperature of from about 130°C to about 165°C for about 24 hours..." See page 3, lines 1-2 and 8-9 of Bermudez. Also, it is clear from the process of preparation of the active extract on page 5 of Bermudez, that heating at temperatures of 130-165°C for a 24 hour period is required to arrive at the active extract. Thus, eliminating the heating step (iii) would go against the clear teachings of Bermudez that this heating step is necessary to obtain the desired therapeutic activity.

Finally, the Examiner has not demonstrated that the product of Bermudez that is administered to humans or animals can be obtained by any of the processes set forth in the present claims. In fact, the product of Bermudez that is administered to humans or animals cannot be obtained by any of the processes set forth in the present claims since none of these processes involve the required step of heating the product at a temperature of 130-165°C for a 24 hour period.

With regard to the secondary references, a skilled person would not combine Bermudez with Kawai since Kawai teaches that the temperature of the sugar cane extract should be kept at or below 120°C. See e.g. p. 4, lines 21 and 55 of Kawai. Bermudez, on the other hand, requires temperatures above 130°C in order to develop the therapeutically active ingredients by heat polymerization. More importantly, even if a skilled person were to combine Bermudez with Kawai, the skilled person would still employ the heating step of Bermudez since one would expect from Bermudez that a heating step above 130°C would be required to develop the therapeutically active ingredients. Thus, a skilled person would have no reason or motivation to administer a composition that had not been heat treated above 130°C in view of a combination of Bermudez and Kawai.

Saska et al. relates to a process for the separation of inositols from sugars and sugar alcohols. Saska et al. applies its process to raw sugar cane extract or an almond hull extract. See col. 1, lines 8-10. Even if a skilled person were to combine Bermudez with Saska et al., the

skilled person would still expect that a heating step above 130°C would be required to develop the therapeutically active ingredients of Bermudez. Thus, a skilled person would have no reason or motivation to administer a composition that had not been heat treated above 130°C in view of a combination of Bermudez and Saska et al. The same arguments apply to Agar et al., Brewer and Kearny.

In addition, Agar et al. relates to a process for the separation of lignins from fibrous plant materials. The skilled person would not be motivated to apply this process to the Bercedin of Bermudez, as suggested by the Examiner, since there is no indication that the Bercedin of Bermudez contains lignins. Thus, the skilled person would have no reason to apply the separation process of Agar et al. to the Bercedin of Bermudez.

Therefore, for the foregoing reasons, the subject matter of claims 153, 166-167, 183, 192-194 and 196-204 is clearly unobvious over Bermudez et al. taken in combination with any of Kawai, Saska et al. Agar et al., Brewer or Kearney.

With regard to the remaining claims 156-162 and 185-191, each of these claims requires that the sugar cane-derived extract is:

(1) a fraction which absorbs light of a wavelength of 420 nm obtainable by column chromatographic treatment utilizing differences in affinity for an ion exchange resin packed in a column as the fixed carrier, and

(2) the sugar cane-derived extract must contain less sugar than a composition from which the sugar cane-derived extract is extracted.

Thus, the subject matter of claims 156-162 and 185-191 differs from the teachings of Bermudez in at least two additional important aspects:

(1) the Bercedin of Bermudez is not a fraction which absorbs light at a wavelength of 420 nm since the Bercedin of Bermudez has not been fractionated, and

(2) the Bercedin of Bermudez is not a sugar-cane derived extract which contains less sugar than a composition from which the extract was extracted since the Bercedin of Bermudez has not been subjected to extraction.

The Examiner takes the position that the teaching on page 10 of Bermudez that the Bercedin can be fractionated renders the present invention obvious. However, even if a skilled person follows the teachings on page 10 of Bermudez and fractionates the Bercedin of Bermudez, two elements of the claimed subject matter are still missing, namely,

(1) there is no teaching in Bermudez to select a fraction which absorbs light at a wavelength of 420 nm, and

(2) there is no teaching in Bermudez of the desirability of obtaining an extract which contains less sugar than a composition from which it is extracted.

In fact, the skilled person would be led away from element (2) by Bermudez, since Bermudez teaches that the polymerized saccharides are the therapeutically active components of the Bercedin composition and thus the skilled person would want to maximize the amount of the polymerized saccharides for this reason.

None of the secondary references to Saska et al. Agar et al., Brewer or Kearney teaches elements (1)-(2) and thus these secondary references cannot cure the deficiencies of the primary reference to Bermudez with respect to these claims.

With respect to the Kawai et al. reference, the skilled person would not combine Kawai with Bermudez for the reasons given above, namely, that Kawai et al. desires to prevent polymerization of the saccharides by maintaining temperatures below 120°C, whereas Bermudez desires polymerization of saccharides and thus includes heating step (iii). Also, although Fig. 2 of Kawai references absorption of light at 420 nm, Kawai does not teach or suggest that by selecting an extract that absorbs light at 420 nm, a product could be obtained having beneficial effects against a disease caused by either an *Escherichia coli* infection or a Pseudorabies infection. Rather, Kawai only suggests that its products can be used as deodorizing compositions. Accordingly, favorable consideration and withdrawal of the rejection of claims 156-162 and 185-191, as amended, is requested.

Favorable consideration, entry of the amendment and issuance of a Notice of Allowance are solicited. Should the Examiner have any questions she is encouraged to call the Applicant's representative listed below.

Respectfully submitted,

Dated: June 5, 2006

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